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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,585	08/10/2005	Hisae Kume	SPO-121	7558
23557	7590	06/29/2006	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			SINGH, SATYENDRA K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/535,585	KUME ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Satyendra K. Singh	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 June 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-17 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 10 August 2005 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Applicant's response filed with the office on June 7<sup>th</sup> 2006 is duly acknowledged.

Claims 1-17 are pending in the application and are examined on their merits, herein, for the elected specie of "**whey protein isolate (WPI)**".

### ***Election/Restrictions***

Applicant's election of a specie "whey protein isolate (WPI)" in the reply filed on June 7<sup>th</sup> 2006 is acknowledged. Because applicant did not distinctly and specifically state whether the election of said specie was made with or without traverse, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

### ***Claim Suggestions***

Claims 7 and 15 recite the limitation "molecular weight of 10,000" but fail to provide the units for molecular weight (daltons or kilodaltons; which is not explicitly stated in the figure legend of Figure 1; see instant specification, page 19, top line, in particular). Appropriate correction is requested.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 14 contain one or more of the trademark/trade name(s) viz:  
**Alkalase** (a registered trademark; see applicant's disclosure, "**Alcalase 2.4L**" from

Novozymes, at page 19, line 31, in particular). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). **The claim scope is uncertain** since the trademark or trade name cannot be used properly to identify any particular material or product. *A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.*

The dependent claims 7-8 and 15-16 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as they depend from claims 6 and 14, respectively.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6-8, 9-11, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al (US 5,714,472, [A]) in view of McCabe (US 6,830,766 B2, [D]) and Davis et al (US 6,998,259 B1, [B]) as evidenced by Fritzsche et al (US 6,737,076 B2; [C]).

Claims are generally directed to a nutritional composition (suitable for liver disease patients, or patients under high level of invasive stress) comprising a milk protein hydrolysate (elected specie, whey protein isolate, obtainable by enzymatic hydrolysis using proteases such as Alcalase and trypsin, ultrafiltration, and HPLC separation as shown in figure 1 of the instant specification) and a protein derived from fermented milk, as proteins; a high oleic acid-containing oil and milk lecithin and/or soy lecithin as lipids; and palatinose (i.e. isomaltulose) as a carbohydrate; and a method of providing nutrition to a patient having liver disease and/or a high level of invasive stress comprising administering said nutritional composition to such a patient (see instant claims 1, 9, and 17).

Gray et al [A] teach an enteral formulation (and method for providing nutrition using a composition comprising high protein, high fat and low carbohydrate; designed for optimized nutrient absorption and wound healing; i.e. for patients under high level of invasive stress) comprising an improved protein source (such as whey protein hydrolysate; see Gray et al, abstract, summary of the invention, column 4; column 5, lines 43-48; examples 2-3, and claims, in particular); a high oleic acid-containing lipid source (as defined in the instant specification on page 14, lines 1-3; such as soy oil; see Gray et al, columns 5-6, in particular) including soy oil and lecithin (see Gray et al, column 5, lines 35-37; examples 1-2, in particular); and carbohydrates (such as maltodextrin and corn starch. It is to be noted that Gray et al recognize the need for optimization of an enteral nutritional composition (suitable for patients under high stress)

in order to reduce the risk of over hydration, hyperglycemia, and carbohydrate intolerance, and hence the emphasis on high protein, high lipid diet (see Gray et al, summary of the invention, column 2, lines 43-55, in particular).

However, a nutritional composition comprising a protein derived from **fermented milk** (as recited in instant claims 3 and 11); wherein the **palatinose** is used as a carbohydrate; and wherein the milk protein **hydrolysate** may be obtained by an enzymatic (using proteases, alcalase and trypsin) hydrolysis of a whey protein isolate (WPI; see instant claims 6-8 and 14-16), is not explicitly disclosed by the referenced invention of Gray et al.

McCabe [D] discloses a high protein food composition (see McCabe, abstract, columns 4-6, and claims, in particular) comprising a protein derived from fermented milk (such as protein from yogurt; see McCabe, see embodiments in columns 5-6, and example 2, in particular), and polyol (such as palatinose or isomaltulose) as a carbohydrate source (see McCabe, column 6, line 1, in particular) in place of simple sugars in order to provide a slowly metabolizable carbohydrate that do not cause a sharp rise in blood sugar level following their ingestion (see McCabe et al, column 4, lines 41-47, claims 20, 29, in particular).

It would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the enteral composition of Gray et al by including palatinose as a carbohydrate, and yogurt as a source of protein derived from fermented milk as explicitly disclosed by the invention of McCabe.

A person of ordinary skill in the art would have been motivated to modify the composition of Gray et al because McCabe provides the benefits of using protein form yogurt (as a protein source and a flavoring agent; see McCabe et al, column 4, in particular), and a polyol (such as palatinose as a slowly metabolizable carbohydrate source in order to avoid a sudden rise in blood glucose level, i.e. suitable for consumption by patients with invasive stress and/or liver disease, see discussion, supra).

The person of ordinary skill in the art would have had a reasonable expectation of success when modifying the composition of Gray et al because McCabe discloses the method of making and incorporation of these components in the high protein nutritional compositions (see McCabe, embodiments disclosed in columns 5-6, and examples 1-2, in particular) that would have been suitable for use in the composition disclosed by Gray et al.

However, a nutritional composition, wherein the milk protein hydrolysate is an enzymatic (using proteases, alcalase and trypsin) hydrolysate of a **whey protein isolate** (WPI; see instant claims 6-8 and 14-16), is not explicitly disclosed by the combined disclosures of Gray et al and McCabe.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Davis et al [B] teach a milk protein hydrolysate which is obtained by the enzymatic hydrolysis of WPI (whey protein isolate such as BiPRO™; see Davis et al,

abstract, summary of the invention, columns 3, 5, 9-10, and claims, in particular) which can be used as a source of antihypertensive peptides (such as having ACE-inhibitory activity) derived from whey proteins (i.e. suitable for use in nutritional compositions for patients under high level of invasive stress).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the composition of Gray et al such that it includes a milk protein hydrolysate which is obtained by enzymatic hydrolysis of a WPI, as explicitly taught by the referenced invention of Davis et al.

A person of ordinary skill in the art would have been motivated to modify the protein source of Gray et al by using the enzymatic hydrolysate of WPI (as disclosed by Davis et al) because Davis et al provide the benefits associated with the use of such hydrolysate obtained from tryptic hydrolysis of whey protein isolate (that have significant antihypertensive properties; see discussion supra).

The person of ordinary skill in the art would have had a reasonable expectation of success in modifying the nutritional composition of Gray et al by substituting the protein source with the milk protein hydrolysate obtained from the enzymatic hydrolysis of WPI because Davis et al disclose the method of preparation of such compositions that can be dried for use in a regimen which comprises oral administration to a mammal such as human or a domestic pet in order to suppress ACE-activity (see Davis et al, column 3, 1<sup>st</sup> paragraph, and columns 9-10, in particular).

The limitations of claims 7-8 and 15-16 (which is a permeate obtained by further treatment with an ultrafiltration membrane having a molecular weight of 10,000 daltons,

and wherein the chromatogram from reversed phase HPLC separation is shown in Fig. 1.) would have been a matter of routine optimization to a person of ordinary skill in the art at the time this invention was made, as evidenced by the disclosure of Davis et al (and as supported further by the invention of Fritzsche et al [C] that discloses the use of alcalase, trypsin ,and other proteases, or combinations thereof to hydrolyse protein sources such as WPI; see column 4, lines 44-65; columns 5-6; example 2-3; and use of ultrafiltration and HPLC separation procedures to obtain the peptides derived from the hydrolysate of WPI) for the preparation of enzymatic hydrolysate of WPI and its use as a component having major health benefits.

As per MPEP 2144.06, *In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).*

As per MPEP 2144.06, "*It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.*" *In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

Claims 4, 5, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al (US 5,714,472, [A]) in view of McCabe (US 6,830,766 B2; [D]) and Siegenthaler [U].

Claims are generally directed to a nutritional composition (for patients having liver disease and/or high level of invasive stress) comprising a milk protein hydrolysate and a protein derived from fermented milk; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin; and palatinose; wherein said fermented milk-derived protein is from **fresh cheese**, wherein said fresh cheese is quark.

The teachings of Gray et al and McCabe have been discussed supra, and are further relied upon in the same manner, herein.

However, a nutritional composition (as recited in the instant claims 4-5 and 12-13) comprising a fresh cheese such as quark as a protein derived from fermented milk, is not explicitly disclosed by the referenced inventions of Gray et al and McCabe.

Siegenthaler [U] discloses the potential nutritive value of cultured dairy products (such as quark cheese and yogurt; see Siegenthaler, abstract, in particular) that are especially suitable for use in children (akin to patients with suboptimal digestive system; in place of fluid reconstituted milk preparations that are linked with lactose-intolerance, or handling-related diarrhea among many populations) as it provides longer shelf-life of the product at ambient temperatures as well as aid in the digestion of residual lactose after ingestion of such fermented milk compositions.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the nutritional composition (as taught by the combined disclosures of gray et al and McCabe) such that the protein derived from fermented milk is from a fresh cheese such as quark as explicitly suggested/disclosed by the invention of Siegenthaler.

A person of ordinary skill in the art would have been motivated to use quark cheese (as a protein source) in the composition of Gray et al (as modified by McCabe;

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see discussion, *supra*) because Siegenthaler provides the benefits and potential values of using fermented milk products such as quark for subjects that have suboptimal digestion capability (such as children), in other words, suitable for a population that requires easily digestible protein source (such as patients under high level of invasive stress and/or liver disease).

The person of ordinary skill in the art would have had a reasonable expectation of success when modifying the nutritional composition of Gray et al (in view of McCabe) because Siegenthaler explicitly suggests the use of fermented milk products such as quark for subjects with less than optimal digestion capability (as is the case with liver patients or patients under high level of invasive stress).

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10/487,237 (from the same inventive entity and same assignee, Meiji Dairies Corp. Tokyo, JP). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-36 in the copending application 10/487,237 are also directed to a composition and methods of using the said composition comprising protein (such as milk proteins), a lipid (such as high oleic acid containing oils, and milk phospholipids), and a carbohydrate (such as palatinose and/or trehalulose). Although, the composition as recited in the copending application 10/487,237 requires certain range of energy percentage supplied from the components (such as proteins, lipids, and carbohydrate), such distribution of the components based on the caloric input would have been a matter of routine optimization to a person of ordinary skill when using the said composition for a particular patient or subject population depending on the nutritional/caloric requirements.

The two sets of claims are largely coextensive, and thus raise an issue of obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

NO claims are allowed.

***Pertinent prior art not relied upon in the Rejections***

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. FUCHS et al. (US 6,592,863 B2; issued on July 15, 2003), Method to provide nutritional composition; abstract, summary, examples and claims.
2. BUCKE et al. (US 4,587,119; issued on May 6, 1986), Method of reducing dental plaque formation with products for human or animal consumption using isomaltulose sucrose substitute; abstract, columns 5-6.
3. Kawai K. et al., Usefulness of palatinose as a caloric sweetener for diabetic patients, Horm. Metabol. Res., 1989, vol. 21: pages 338-340; see introduction and discussion, in particular.
4. OJIMA et al. (US 7,029,717 B1; issued on April 18, 2006), Sucralose-containing composition and edible products containing the composition, abstract, columns 7-8, in particular.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh  
Patent Examiner  
Art Unit 1651

JEAN C. WITZ  
PRIMARY EXAMINER